UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

UNITED STATES OF AMERICA, Plaintiff, v. PHILIP MORRIS USA INC., f/k/a PHILIP MORRIS INC., *et al.*, Defendants.	)	Civil Action No. 99-CV-2496 (GK) Next Scheduled Court Appearance. Trial (ongoing)

NOTICE OF FILING THE WRITTEN DIRECT
EXAMINATION OF ANTHONY ALBINO, PH.D *(REDACTEDVERSION)*

Pursuant to Order No. 471A, Defendant Liggett Group Inc. herewith files the Redacted Version of the Written Direct Examination of Anthony Albino, Ph.D.

Dated. New York, New York
March 14, 2005

Respectfully submitted,

By: */s/ Peter A. Woolson*

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WRITTEN DIRECT EXAMINATION OF
ANTHONY ALBINO, PH.D. SUBMITTED PURSUANT
TO ORDER # 471A *(REDACTED VERSION)*

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I. BACKGROUND INFORMATION

Q. Please state your full name for the record.

A. Dr. Anthony Albino.

Q. What is your current occupation?

A. I am currently the Senior Vice President of Public Health Affairs at Vector Tobacco Inc. ("Vector").

Q. In broad terms, what are your duties as Senior Vice President of Public Health Affairs at Vector?

A. I direct Vector's biological testing and research efforts. I also lead the company with respect to its interactions with public health authorities.

Q. Could you please explain your understanding of the relationship between Vector and one of the defendants in this case, Liggett Group Inc. ("Liggett")?

A. Vector and Liggett are affiliates. They are separate companies, but they are both owned by the same ultimate parent company known as Vector Group Ltd.

Q. Dr. Albino I'd like you to tell the Court a little bit about your educational background and experience. Please tell the Court about your education beginning with college.

A. I received a B.A. degree in biology from Hunter College in 1970. I also received a Ph.D. degree in cancer biology from Cornell University in 1974. I have been involved in cancer research for my entire professional career.

Q. After you received your doctorate, did you receive any additional training?

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A. Yes, from 1974 to 1978, I was a post-doctoral fellow at the Hospital for Special Surgery in New York City. Then, in July of 1978, I joined the staff of the Memorial Sloan-Kettering Cancer Center ("Sloan-Kettering") where I remained until 1995.

Q. What position did you hold while at Sloan-Kettering?

A. I held a number of positions. I began as a research associate and later became an Assistant Member in the Department of Immunology.

Q. What were you duties as an Assistant Member in the Department of Immunology?

A. I was the head of a laboratory where I conducted and supervised my own research.

Q. What type of research did you conduct while at Sloan-Kettering?

A. All of my research related to understanding various aspects of human cancer. This research primarily focused on basic science and immunological approaches. However, I have also been involved in several clinical trials.

Q: At Sloan-Kettering did you have any involvement with smoking related diseases?

A: Yes. I performed research on several different types of cancers associated with smoking, including lung, esophageal and other head and neck cancers.

Q. Have you published any articles or books concerning your research?

A. Yes, I have published numerous articles in scientific and academic journals concerning cancer research and related issues. Most of these articles have been the subject of peer-review.

Q. Who funded your research at Sloan-Kettering?

A. Because Sloan-Kettering did not fund research itself, I was responsible for acquiring funding from outside sources. Typically funding would come from federal grants or private foundations.

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Q. What organization funded your last research grants before you left Sloan-Kettering?

A. My last research grants while at Sloan-Kettering were primarily funded by the National Cancer Institute.

Q. What did you do in 1995 after you left Sloan-Kettering?

A. I became the Director of Research in the Department of Otolaryngology at the Manhattan Eye, Ear and Throat Hospital in New York City, a position I kept until 1997.

Q. What type of work did you do as Director of Research at the Manhattan Eye, Ear and Throat Hospital?

A. I worked principally as the director in charge of basic science research.

Q. You said you kept your position at the Manhattan Eye, Ear and Throat Hospital until in 1997. Did you take a position somewhere else after that?

A. Yes, in the Spring of 1997, I was recruited by American Health Foundation Cancer Center in Valhalla, New York to be the Director of Research. I stayed in that position until 2001.

Q. What is the American Health Foundation Cancer Center?

A. The American Health Foundation Cancer Center was one of ten National Cancer Institute designated basic science cancer centers in the United States. It was founded by Dr. Ernst Wynder, who was a pioneer in the area of tobacco-related cancer research. Its primary mission is to conduct and fund research on issues concerning tobacco-induced cancers, including such subject matters as their etiologies and causes of cancer, and their prevention and treatment. It also performed many seminal studies as to the chemical composition of tobacco smoke.

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Q. What were your duties as Director of Research at the American Health Foundation?

A. I was in charge of its research programs and major grant applications to the National Cancer Institute. I was involved in making determinations concerning the nature and quality of research at the Foundation. In addition to supervising different aspects of cancer research, I was also responsible for administrative and fundraising duties related to cancer research. One of my main roles was applying for federal grants for cancer research conducted by or on behalf of the American Health Foundation. I also had my own research program.

Q. Did you have any other duties while you served as Director of Research at the Foundation?

A. Yes. I also served Director of the American Health Foundation Division of Shared Resources (from 1998-2001); as Deputy Director of the American Health Foundation Cancer Center (from 1999-2001); and as Research Professor of Dermatology in the Department of Dermatology at the New York Medical College (from 1997-2001). I also served on numerous National Cancer Institute review committees and served as Chairman of Subcommittee C of the National Cancer Institute (from 1999-2001).

Q. What is NCI's Subcommittee C?

A. It is one of NCI's major review committees for review of all basic science and preclinical program grants. After large, usually multi-center, grants undergo initial review by specialized committees, they then go to Subcommittee C for ranking and prioritization. Subcommittee C basically decides which the best grants are and which merit the limited funding available.

Q. To your knowledge, has the American Health Foundation studied smoking and health issues?

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A. Yes, the study of smoking related diseases was a major focus of the Foundation. In fact, Dr. Ernst Wynder, who is considered to be one of the preeminent figures in smoking and health research, was the founder of AHF. Dr. Wynder himself was responsible for publishing numerous important scientific journal articles on the issue of smoking and health. Smoking and health research was an issue that was of paramount importance to Dr. Wynder and that translated to the work done at the AHF.

Q. Did you have an opportunity to work with Dr. Wynder at the Foundation?

A. Yes. My work at AHF allowed me the opportunity to work closely with Dr. Wynder as well as other experts in the field of cancer research.

Q: Prior to your work at Vector, was any of your work or research done for or on the behalf of any tobacco company?

A: No, it was not.

Q. What did you do after you left the American Health Foundation?

A. I joined Vector in 2001.

Q. What prompted you to join Vector?

A. In 2001, I was approached by Bennett LeBow, the Chief Executive of Vector, who was leading the company's efforts to develop a cigarette with reduced carcinogens. Mr. LeBow told me he wanted someone with significant expertise in cancer research to spearhead Vector's biological research, and he thought that I could fit that role.

Q. Had you known Mr. LeBow prior to this time?

A. Yes. I had met him previously.

Q. When was that?

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A. About a year or so earlier, Mr. LeBow had approached the American Health Foundation about conducting research and developing a cigarette with reduced carcinogens.

Q. Who at the American Health Foundation did Mr. LeBow approach?

A. Mr. LeBow approached Dr. Daniel Nixon, the Foundation's director at that time. I was present at a meeting, along with Dr. Nixon, Dr. Dietrich Hoffman and others, where Mr. LeBow conveyed his interest in funding research to develop a cigarette that had a reduced level of carcinogens.

Q. Did the Foundation agree to work with Mr. LeBow on such a project?

A. No.

Q. Were you made aware of the reason the Foundation did not back Mr. LeBow's project?

A. Yes. Although many of the scientists, including myself and Dr. Hoffman were interested in working to develop a safer cigarette, the Board of Trustees of the Foundation did not want to conduct research that involved funding by a tobacco company.

Q. Turning back to your decision to work for Vector, after Mr. LeBow initially approached you about employment at Vector, how many times did you meet with him before joining Vector?

A. In addition to several phone conversations, I met with Mr. LeBow I believe three times before agreeing to join Vector.

Q. Did Mr. LeBow tell you about the position he wanted you to fill?

A. Yes, we discussed the parameters of the position in great detail.

Q. What did he tell you?

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A. In sum, Mr. LeBow told me that Vector wanted to develop a cigarette with reduced carcinogens. Part of that plan was to look into advancing certain research that was conducted by Liggett in the late 1970s and early 1980s involving the implementation of a palladium catalyst to reduce carcinogens in a cigarette. He expressed to me that he wanted a scientist that had significant expertise in cancer research and in the mechanisms of the cancer causation process to supervise its biological testing program for potential reduced risk cigarette products. Additionally Mr. LeBow wanted a scientist capable of communicating and explaining the science to both the scientific and lay community.

Q. Why did you decide to leave the Foundation and work for Vector?

A. I believe that perhaps the greatest contribution to be made to research on cancer and its prevention would be the development of a reduced risk or safer cigarette product. I viewed the opportunity at Vector, and still do, as an opportunity to work on a new and exciting component of cancer research. In order to develop reduced risk cigarette products, significant questions in cancer research need to be answered and tough problems need to be solved. There would be much difficult and innovative biological research to be done in order to accomplish that goal, and I was motivated by the challenge of the project.

Q. Dr. Albino, have you ever testified at a trial before?

A. No, I have not. I have been deposed twice in this action, and a few times in other smoking and health litigations, but I have never testified at trial.

Q. And, Dr. Albino, are you being paid in connection with your time or work in connection with this case?

A. The short answer is no. I will point out that I am a full-time employee and officer of Vector, and I am paid in connection with my work at Vector. I am also being reimbursed by

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Liggett for my travel expenses. But I am not being paid separately for my time preparing for or testifying in this action.

II. RESEARCH AND DEVELOPMENT EFFORTS AT VECTOR

Q. Dr. Albino, do you believe that smoking cigarettes is a cause of disease?

A. Yes, I do.

Q. Do you believe that smoking cigarettes is a cause of lung cancer?

A. Yes, I do.

Q. Are you familiar with the positions of Vector and Liggett as to whether smoking cigarettes is a cause of disease?

A. Yes. Liggett and Vector both take the public position that cigarettes are a cause of lung cancer and other serious diseases, and that smoking is addictive. Both companies have stated publicly that they agree with the positions on these issues as stated by the United States Surgeon General and the public health authorities.

Q. Do you know when Liggett first took the position that smoking cigarettes was a cause of disease and is addictive?

A. Well, I only became employed by Vector in 2001, so I am not fully aware of Liggett's historical position on such issues. I am generally aware that, prior to my employment with Vector, Mr. LeBow made public statements that cigarettes are a cause of lung cancer and other serious diseases, and that smoking is addictive. I also know that this has continued to be the public position of Liggett and Vector since I began my employment with Vector.

Q. Could you describe in general terms the research and development efforts at Vector?

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A. Yes. The principle objective at Vector is the development of alternative cigarette products in an effort to promote smoking cessation and reduced cancer risk.

Q. In your view, what is a reduced risk cigarette?

A. A cigarette that can be shown through reliable and systematic scientific evidence to reduce some or all of the health risks associated with smoking cigarettes.

Q. Describe Vector's efforts for the development of a "reduced risk cigarette."

A. Well, Vector has thus far developed and brought to market two alternative cigarette products which we believe have the potential to reduce risk. In November 2001, Vector launched a cigarette under the brand-name Omni. Omni had reduced levels of certain key carcinogens in cigarette smoke when compared to other conventional cigarettes available on the market. Additionally, in early 2003, Vector launched a product known as Quest. Quest utilizes genetically modified tobacco which contains virtually no nicotine. These are two different types of products that operate in very different ways. Omni was designed to reduce exposure to certain carcinogens in smoke. Quest was designed to reduce exposure to nicotine. In addition to these specific products, Vector is conducting additional research to attempt to reduce risk in cigarette products. For example, Vector is trying to identify novel biomarkers that can clarify how tobacco smoke causes disease.

III. DEVELOPMENT OF OMNI

Q. Okay, I'd like to talk about the development of Vector's Omni brand cigarette. Was Omni being manufactured for sale at the time you joined Vector?

A. No, when I came to Vector, Omni was still in development.

Q. And when you came to Vector, did you become involved with the research and development of Omni?

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A. Yes. There had been a team of scientists, primarily organic chemists, working on Omni when I came to Vector, but I did become involved to some degree in the development of Omni when I came aboard.

Q. Please tell the Court what you understood the goal of Vector was in developing the Omni cigarette?

A. As I said earlier, the ultimate long-term goal with respect to Omni was to create a cigarette that reduced the risk of disease when compared to a conventional cigarette. There were more immediate steps to achieve along the way toward attaining that goal. The theory behind Omni was that there are groups of very potent carcinogens that are found in cigarette smoke, in particular the class of carcinogens known as the polycyclic aromatic hydrocarbons (or "PAHs"), but there are several others as well. The public health authorities had for a very long time identified PAHs as a class of carcinogens in cigarette smoke that were associated closely with lung cancer risks. It was thought that Omni had the potential to reduce risk for smokers who used it, as the Omni catalyst system reduced significantly the yields of certain groups of carcinogens in cigarette smoke, most particularly PAHs, and yet appeared to maintain a level of consumer acceptability.

Q. In broad terms, how did Omni reduce the yields of certain carcinogens in the cigarette smoke?

A. The mechanism of how the Omni reduces the yields of the certain carcinogens involves some very advanced chemistry and cigarette design techniques which, to some extent, is beyond my expertise. In broad terms, there is a solution which is added to the tobacco which acts as a catalyst, and alters the combustion process that takes place in the cigarette and prevents the formation of certain carcinogens like the PAHs.

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Q. In your earlier answer, you mentioned the phrase "maintain a level of consumer acceptability" in the context of developing Omni. What did you mean by that?

A. Well, there may be many different methods to reduce or even eliminate PAHs or other carcinogens from cigarette smoke. But if you cannot achieve those reductions in the context of a consumer acceptable cigarette product, no one will buy it or use it, and then your goal will not have been met. Unlike many so-called "reduced risk" cigarettes that other companies had worked on in the past, which very much changed how the cigarette functioned (such as by heating instead of burning tobacco), the design parameters for the Omni were to create a cigarette that tasted, smoked and burned like other premium cigarettes, but still had reduced levels of certain key carcinogens.

Q. What was your role in the research and development of Omni?

A. In broad terms, there were different teams working on the research and development for Omni. There were scientists involved in the cigarette design who were working on the technical aspects of creating the Omni cigarette. This included the creation of the catalyst system, the physical parameters and components of the cigarette, the blends of the tobacco, the taste characteristics, the chemical testing of the constituents of the smoke, etc. My work involved the biological testing for Omni. This included an assessment of how Omni performed in biological testing protocols, such as genetic tests and mouse skin painting studies. Although I was not directly involved in the cigarette design for Omni, my department collaborated with the cigarette designers in the testing of the product.

Q. You mentioned earlier that Omni developed from certain research conducted by Liggett in the late 1970s and early 1980s involving a palladium catalyst. Are you familiar with the research conducted by Liggett in the past with respect to the palladium catalyst?

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A. I am generally aware that Liggett conducted research with respect to the development of a palladium catalyst cigarette in the 1970s and 1980s, and that the project was referred to, among other things, as the XA Cigarette or Project XA. I understand that Vector scientists began their work on Omni by looking at what Liggett had been doing back in the 1970s and 1980s with respect to a catalyst cigarette. I have reviewed some of Liggett's historical research materials relating to Project XA. I have also had communications with some of the chemists at Vector who were directly involved in developing the catalyst process for the Omni. However, the chemists who were more intimately involved in the cigarette design of the Omni have more knowledge about Liggett's efforts in the 1970s and 1980s with respect to XA than I do.

Q. To what extent did Vector's research and development for Omni relate to Liggett's XA Project?

A. As I said, my understanding is that Liggett's Project XA was a starting point for the chemists and cigarette designers at Vector who were trying to develop the catalyst and other parameters for Omni, but much additional original research had to be conducted at Vector in order to develop Omni. The chemists and cigarette design people who were working on Omni did not believe that Liggett's Project XA had created a cigarette that was ready to be marketed, and much additional work was required for Omni.

Q. How much additional work went into developing the Omni at Vector?

A. That is difficult to quantify. We know that hundreds of experiments were conducted by the cigarette design team and perhaps thousands, if not tens of thousands, of laboratory hours went into the development of the catalyst and other design parameters for Omni. We also know that the technology available today is very different than what was available to Liggett back in

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the 1970s and 1980s. In sum, tens of millions of dollars were spent on the research and development aspects of the cigarette design and testing protocols for Omni.

Q. Was Vector ultimately successful in developing a cigarette that had reduced levels of certain carcinogens?

A. Yes. Vector was successful in developing a cigarette that had reduced levels of certain key carcinogens, specifically PAHs, in its cigarette smoke when compared with other leading brands on the market. Vector conducted numerous smoke chemistry analyses using a variety of different methodologies (including the FTC, Massachusetts and Canadian Intense Methods) which demonstrated that certain key carcinogens were reduced in the mainstream and sidestream smoke of the Omni when compared with leading conventional brand cigarettes.

Q. Did Vector conduct any tests to determine whether the use of the Omni catalyst or other design features introduced any unique toxins or carcinogens into the Omni smoke as compared to conventional cigarettes?

A. Yes. Vector conducted chemical smoke analyses on Omni to see if unique toxins or carcinogens were introduced into the Omni smoke. Vector found that there was no evidence that the Omni introduced unique toxins or carcinogens into cigarette smoke when compared with conventional cigarettes. There were essentially the same carcinogens and toxins in Omni smoke that appeared in conventional smoke, but in different yields.

Q. Were any carcinogens or toxins actually increased in the Omni?

A. Yes. When you compare the same cigarette, both with and without the Omni catalyst technology, a few carcinogens and other toxins were found to increase in the version which utilized the catalyst technology, while several other carcinogens were found to have decreased. For example, Formaldehyde, which is a carcinogen, was found to increase in the Omni which

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used the catalyst. Nitric oxide, which is a toxin but is not designated in the United States as carcinogen *per se*, was also shown to have higher levels in the Omni with the catalyst technology. However, the increases in carcinogen and toxin levels in the Omni were not significantly different or higher than what appeared within the range found in conventional cigarettes.

Q. Were the increased levels of formaldehyde and nitric oxide of concern to Vector?

A. Ideally we would have liked to have decreased or even eliminated those constituents of the cigarette smoke, if possible. However, because formaldehyde and nitric oxide are well known constituents of conventional cigarette smoke, their continued appearance in the cigarette smoke of Omni in comparable levels as appear in conventional cigarettes did not undermine the overall achievement of Omni.

Q. In addition to conducting chemical analyses on Omni smoke, did Vector conduct biological testing on the Omni?

A. Yes. Vector conducted very specific biological testing to determine the carcinogenicity of Omni smoke in laboratory animals. One such test was the Dermal Tumor Induction Test On SENCAR Mice. That study looked at the carcinogenic potential for Omni cigarette smoke condensate in scientifically accepted mouse models. The results showed a dramatic reduction in carcinogenicity for Omni when compared to conventional cigarettes. Specifically, the tests showed that Omni smoke had a significant reduction in the ability to induce tumors in laboratory animals when compared to the smoke of leading conventional brand cigarettes.

Q. Did Vector ever conduct studies on actual human smokers in an attempt to determine whether Omni smokers had a difference in their risk for disease?

A. No.

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Q. Why not?

A. In part because there is no scientific protocol presently for conducting such a test. There is certainly no guidance from any regulatory agency on how to conduct such testing on human beings. Additionally, given the current technology, the only methodology that I am aware of to assess the relative risk of Omni would be to perform long term epidemiological studies on human smokers of Omni as compared to smokers of conventional cigarettes. Such a study would, in any event, take many years to complete.

Q. You said earlier that Omni was marketed in November 2001, is that correct?

A. Yes, I believe so.

Q. You testified earlier that "the ultimate goal for the Omni was to create a cigarette that had reduced risk of disease when compared to a conventional cigarette." Did Vector believe that it had achieved that goal when it launched Omni in November 2001?

A. No, it did not. Although the ultimate long term goal for the Omni was to create a "reduced risk" cigarette, there was insufficient scientific evidence to support that claim when Omni was launched in November 2001. Instead, by November 2001, Vector had accomplished what it believed was an interim step, which was an Omni cigarette that had reduced levels of certain key carcinogens in the cigarette smoke when compared with conventional brands.

Q. And when Omni was sold to the public, was Omni marketed as a "reduced risk" cigarette?

A. No, it was not. Omni was carefully marketed to the public as a cigarette that had reduced levels of certain carcinogens. Beyond the congressionally-mandated warning labels, Vector included additional warnings in Omni advertisements which stated: "Smoking is addictive and dangerous to your health. Reductions in carcinogens (PAHs, nitrosomines, catechols and

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organics) have NOT been proven to result in a safer cigarette. This product produces tar, carbon monoxide, other harmful products and increased levels of nitric oxide." Vector also made public on its website the ingredients of the Omni, an explanation of the limitations of the Omni as a "safe cigarette" and the detailed results of Vector's carcinogen reduction testing program, which identified the yields of the key constituents of the cigarette smoke in Omni utilizing three different methodologies: the FTC Method, the Massachusetts Method and the Canadian Intense Method. Additionally, as Vice President of Public Health Affairs, I made several presentations concerning the science of Omni to the states' attorneys general and other public health authorities. At least some of these presentations were open to the public and to other tobacco company manufacturers. These presentations were detailed and disclosed, among other things, the results of the chemical and biological testing of the Omni. We explained what Vector believed it had achieved in creating a reduced carcinogen cigarette, but also identified the limitations of what was known about the Omni.

Q. I would like to show you what has been identified as Liggett Exhibits 548 and 549. Can you identify these for the Court?

A. Yes, these are two of several powerpoint presentations that I gave to public health authorities and other governmental representatives concerning the Omni cigarette. Liggett Exhibit 548 is a powerpoint presentation that I gave to representatives of the Federal Trade Commission on January 15, 2002. Liggett Exhibit 549 is a powerpoint presentation that I gave to representatives of the National Association of Attorneys General on June 6, 2002.

Q. Did anyone at these presentations dispute the validity of the research that you described?

A. No.

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Q. Subsequent to your presentations, are you aware of any criticism from the public health community concerning the marketing of Omni by Vector?

A. I am generally aware that there was concern and criticism by certain governmental authorities suggesting that Vector was making implied health claims in its advertising of the Omni.

Q. Has Vector ever made any health claims for Omni, implied or otherwise?

A. No. Vector was very careful to communicate to scientists, the public health community and to consumers that Omni is a cigarette that has identifiable reductions in certain carcinogens in its cigarette smoke in certain test protocols. Vector did not advance any claim that a smoker of Omni has a reduced risk of disease, or any other health claim. In fact, Vector took steps to explain and to warn consumers about the limitations of Omni.

Q. Now I'd like to discuss how Omni performed in the market. Are you aware of whether Vector is currently manufacturing, marketing or selling Omni cigarettes?

A. Vector is not currently manufacturing, marketing or selling Omni cigarettes.

Q. Why is that?

A. My understanding is that sales volume for Omni was very low, much lower than Vector had hoped or expected. Essentially, it was a commercial failure and Vector determined to cease manufacturing, marketing or selling it. However, research relating to improving Omni's catalyst system and other design attributes continues at Vector.

IV. DEVELOPMENT OF QUEST

Q. Dr. Albino, I'd now like to discuss the product you mentioned earlier called Quest. Does Vector currently manufacture and market Quest?

A. Yes.

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Q. And have you been involved in some of the research and development efforts of Quest.

A. Yes.

Q. Could you please tell the Court how Quest is different from conventional cigarettes?

A. The Quest cigarette product, which is sold in styles Quest 1, Quest 2 and Quest 3, contains, in varying amounts, genetically modified tobacco, which tobacco contains virtually no nicotine. All of Quest cigarettes have reduced levels of nicotine as compared to conventional cigarettes, resulting principally from the use of the genetically modified tobacco. The three style types, Quest 1, Quest 2 and Quest 3, have descending levels of nicotine while tar levels remains essentially constant. Utilizing the FTC Method, Quest 1 has approximately 0.6 mg of nicotine; Quest 2 has 0.3 mg of nicotine; and Quest 3 had no more than 0.05 mg of nicotine.

Q. Prior to the development of this genetically modified tobacco, were you aware of any way to eliminate virtually all nicotine from tobacco?

A. I was generally aware of the use of light and ultra light cigarettes, which reduce both the tar and nicotine yields of the cigarette, but I was not familiar with the drastically reduced levels of nicotine which can be achieved in Quest using genetic engineering.

Q. How much nicotine does Quest 1 have compared to the lightest conventional cigarettes available on the market?

A. My understanding is that the lightest conventional cigarettes on the market have approximately 1 mg of nicotine utilizing the FTC Method. Quest 1, which is the highest nicotine yielding product in the Quest family, has twenty percent less nicotine than a conventional light cigarette using the FTC Method.

Q. How is Vector able to create a cigarette with so little nicotine?

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A. I have not been involved directly in the genetic technology behind the Quest, but my understanding is that Vector contracts with farmers to grow tobacco that is genetically modified, so that the tobacco has very low levels of nicotine. This tobacco is then incorporated into the design and manufacture of the different versions of Quest.

Q. Why did Vector want to create a product with little or no nicotine levels?

A. Well, nicotine is considered a pharmacologically active ingredient in cigarette smoke which contributes to addiction. So the hypothesis is if you can reduce the nicotine level in cigarette smoke, you may be able to reduce addiction or addiction risk in smokers. In particular, one of the ultimate goals for Quest is to develop it into a smoking cessation device, where someone could use the three cigarette styles of Quest (1, 2, and 3) to wean off of nicotine.

Q. Do you know if people in the public health field have advocated the availability of a ultra-low or no-nicotine cigarette that consumers would actually smoke?

A. Yes, I would not say that there has been a unified voice on this subject. But at different points in time, various public health authorities have advocated the reduction in nicotine levels in cigarette smoke.

Q. Doctor I'd like to show you a document that has been marked as LGI 624 which is a 2003 article published in *Nicotine & Tobacco Research* and entitled "Effects of low nicotine content cigarettes on smoke intake." Are you familiar with this document?

A. Yes.

Q. It lists the authors as Jed E. Rose and Frederique M. Behm, are you familiar with either of these authors?

A. Yes, very well.

Q. How do you know Drs. Rose and Behm?

http://legacy.library.ucsf.edu/tid/mor07a00/pdf
Source: https://www.industrydocuments.ucsf.edu/docs/jxjl0001

A. Dr. Rose is, in my estimation, one of the premier scientist in this country dealing with smoking cessation. He is the authority on the subject.

Q. Did Vector conduct any studies on Quest?

A. Yes. Vector has conducted smoke chemistry analyses and quality control testing on Quest to ensure and confirm, among other things, the levels of nicotine in the cigarette that it reports. Vector has also performed, and is continuing to perform, some highly specialized smoking cessation and compensation studies regarding Quest to see whether Quest may be appropriate to use as a smoking cessation device.

Q. Dr. Albino, what is compensation in the context of cigarette smoke?

A. It is a broad concept, but I will try to give you a working definition. Compensation means that a smoker will seek to maintain the satisfaction of cigarette use when something in the cigarette design has changed. For example, if we lower tar levels in a conventional cigarette, compensation suggests that a smoker may alter the way that the cigarette is smoked (by perhaps inhaling more deeply, or by smoking the cigarette longer) in order to achieve the previous satisfaction level. That is one example. Another is that a smoker may increase the number of cigarettes to achieve the previous level of satisfaction. There has been a great deal of study into the area of smoker compensation and it is a complex area.

Q. Why is compensation important in the context of Quest?

A. Well, Quest has drastically reduced nicotine yields. If smokers compensate when using Quest, then it would be possible, among other things, for the smokers to frustrate the ultimate goal of reducing their nicotine intake. Understanding how smokers may or may not use compensation with Quest is a very important part of understanding whether Quest can be a useful smoking cessation device.

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Q. Who was in charge of the smoking cessation and compensation studies regarding the Quest?

A. My role at Vector is to supervise the overall studies of Quest as a potential smoking cessation device. In this connection, Vector has given non-restricted funds to Duke University to support various research studies of Dr. Jed Rose, who has specialized expertise in this area. Additionally, Vector has retained other outside scientists and consultants to do participate in the overall research on Quest as a smoking cessation device.

Q. I'd like to show you what has been identified as LGI Exhibit 532, which I believe is a memo from you to Mr. LeBow concerning some compensation data accumulated from Dr. Rose regarding the Quest. Have you seen this document before?

A. Yes.

Q. And what does it show?

A. The preliminary data from Dr. Rose at that time demonstrated that the smokers who used Quest were generally successful in reducing their overall intake of nicotine. Essentially, smokers who used Quest were generally found not to compensate for the reduced levels of nicotine.

Q. Why does the memo refer to OMNI-NICOTINE FREE and not to Quest?

A. Because at that time, the working name for what ultimately became Quest was "OMNI-NICOTINE FREE." However, just to be clear, the memo is not referring to the Omni cigarette that we discussed earlier in my testimony, but is referring to what we have been discussing as Quest.

Q. I would like to show you what has been marked as LGI Exhibit 637. Have you seen this document before?

http://legacy.library.ucsf.edu/tid/mcn07a00/pdf Document hosted at www.industrydocuments.ucsf.edu/docs/jxjl0001

A. Yes, it is a powerpoint presentation made by Dr. Rose to Vector concerning his research on Quest.

Q. I would like to direct your attention to page LGX 007802. Can you tell the Court what appears on that page?

A. Yes, that is a summary of Dr. Rose's study results at that point in time which he communicated to Vector. Essentially there were four study results: that there was "no compensation observed with Quest cigarettes;" that Quest cigarettes effectively relieve craving;" that there were "low desirability ratings consistent with prediction of low abuse liability;" and that "affect withdrawal symptoms suggest concurrent use of NRT (or nicotine replacement therapy) may be beneficial."

Q. Did Vector also conduct studies concerning the consumer acceptability of Quest?

A. Yes.

Q. What did the results of those studies show?

A. Generally, Quest has very high consumer acceptability notwithstanding the delivery of relatively low nicotine yields.

Q. Is Quest sold throughout the country?

A. No it is not. I am not directly involved in the marketing of Quest, but my understanding is that Quest is currently marketed in seven test market states.

Q. Does Vector advertise and market Quest?

A. Yes, it does. Although Vector identifies the reduced levels of nicotine available in the different Quest products, it expressly warns that it is not a "smoking cessation device."

Q. Why is that?

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A. The testing on the efficacy of Quest as a smoking cessation device are not yet complete, so it would be premature to market Quest as such.

THE FOLLOWING TESTIMONY HAS BEEN FILED UNDER SEAL: 23:1-24:10

http://legacy.library.ucsf.edu/tid/mcn07a00/pdf Substantial portions www.industrydocuments.ucsf.edu/docs/jxjl0001

Q. How much has Vector spent so far in developing and marketing the Quest cigarette to consumers?

A. I don't have the precise numbers, but the figure is in excess of $50 million dollars.

V. VECTOR TODAY

Q. As part of your duties as Vector today, are you involved in any other smoking and health projects that we have not yet talked about?

A. Yes.

Q. What other projects are you currently involved with at Vector?

A. We spoke about the Omni earlier. One of the central problems that we had with Omni was that there was no adequate biological testing protocol for determining whether such a cigarette was in fact a "reduced risk" cigarette. So Vector is involved in some very sophisticated biological and genetic research to try to develop a better method for understanding, at a molecular and genetic level, what types of exposure causes cancer and how that exposure may cause cancer.

Q. Can you give us a specific example?

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A. Sure. One of the issues in cancer etiology in relation to cigarette smoke is understanding the specific types of molecular damage that are most relevant to the cancer induction process. So we are doing very extensive basic science research in multiple areas to determine if we can predict what may trigger a cell into becoming malignant. If we can more firmly understand the specific and sequential steps a cell must traverse in order to become malignant, we will be in a much better position to design and test a reduced risk cigarette.

Q. Is this work performed at Vector by Vector scientists?

A. This work is being performed at Vector by Vector scientists and by outside collaborators and laboratories, but who operate under my general direction.

Q. When it came to deciding the types of research projects to pursue, who in your department has the final say?

A. I do. I alone have sole responsibility for directing the biological research at Vector.

Q. Has that been true since you started at Vector?

A. Yes.

Q. Who determines how much you can spend on the research you conduct at Vector?

A. I am provided with a budget by Mr. LeBow.

Q. Does Mr. LeBow or anyone else tell you how you can use the budget allotted to your department?

A. No, I have sole discretion. With the exception perhaps when my department requires an unusually large sum of money, say for a major piece of equipment. Other than that, I have full control over how the research money is used.

Q. Do you have to get permission from anyone at Vector if you want to implement a new research program?

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A. No, I've never asked permission to start any of my research.

Q. Does Mr. LeBow have any involvement in how Vector's research budget is used?

A. Mr. LeBow is informed and keeps abreast of the research conducted by Vector. However because Mr. LeBow is not a scientist, he relies on the scientists that work for him, like myself, to explain the scientific rationale beyond the projects.

Q. What is the budget for your department at Vector currently?

A. Approximately four million dollars per year.

Q. Thank you Dr. Albino. I have no further questions.

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